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10/506,380	09/02/2004	Helene Lannibois	RN01019	2747

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EXAMINER

KAROL, JODY LYNN

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1609

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,380

Applicant(s)

LANNIBOIS ET AL.

Examiner

Jody L. Karol

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/FR02/00769, International Filing Date: 3/4/2002. Claims 1-18 have been cancelled and claims 19-36 have been added as per applicant's preliminary amendment dated 9/2/2004. Accordingly, claims 19-36 are pending and examined on the merits herein.

Information Disclosure Statement

1. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining

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compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Priority

2. Applicant has not claimed priority to prior foreign application FR 01 02397, filed on 2/21/2001. It is noted that the applicant is not eligible for foreign priority since PCT/FR02/00769 was filed more than twelve months after FR 01 02397.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words.

Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: the specification does not follow the proper guidelines for the preferred arrangement of the

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specification. Specifically, the specification does not include any headings identifying the subject matter (i.e. Background of the Invention, Brief Summary of the Invention, etc.) Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

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5. The use of the trademarks Arlacel®, Ultraturrax®, Arlatone®, Rhodopol®, and Alkamuls® have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 19-21 and 25-26 the term "and/or" is simultaneously inclusive and exclusive. It is unclear if the component or limitation immediately following the "and/or" term must be present. For examination purposes, the "and/or" term will be interpreted as "or" in that the component or limitation is optionally present. Claims 22-24 and 27-36 are rejected for being dependent on a rejected base claim.

In addition, claim 21 recites that the quantity of nonionic surfactant and/or nonionic amphiphilic polymer represents 2 to 10% by weight of the internal aqueous phase. However, there is no nonionic surfactant or nonionic amphiphilic polymer necessarily present in the internal aqueous phase. These components are present in

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the external aqueous phase and the internal oily phase provided the amphiphilic polymer present is nonionic. It is unclear if the weight % range is referring to the **total quantity** of the nonionic surfactant and nonionic amphiphilic polymer, or if the claim is referring to only the quantity of nonionic surfactant or nonionic amphiphilic polymer present in the **external aqueous phase**. For examination purposes, the weight % range is interpreted to refer to the quantity of nonionic surfactant or nonionic amphiphilic polymer present in the **external aqueous phase**.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-11 of U.S. Patent No.

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7,101,931 B2 in view of Nadaud et al. (US 5,567,426). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to cosmetic or dermatological formulations comprising a water/oil/water mixed emulsion while the patented claims are drawn to a granule made by the process of drying a water/oil/water mixed emulsion. The mixed emulsion of the instant claims comprises an internal aqueous phase containing at least one hydrophilic active material, dispersed in an internal oily phase containing at least one nonionic surfactant or at least one amphiphilic polymer, the whole being dispersed in an external aqueous phase containing at least one soluble or dispersed active material and at least one nonionic surfactant, nonionic amphiphilic polymer, or anionic amphiphilic polymer. The specifications for the mixed emulsion of the instant claim 19 substantially overlaps with the mixed emulsion of the patent claim 1, except that in the patented claim, the external aqueous phase does not necessarily comprise an active material, unless the water-soluble or water-dispersible polymer is considered to be an active material. However, multiple emulsions are a well-known means of introducing two active materials into the same formulation, where one active material is present in the internal aqueous phase and the other is present in the external aqueous phase. Nadaud et al. discloses water/oil/water multiple emulsions that comprise active substances into both the internal and external aqueous phases (see abstract, column 10, lines 41-49, and examples). Therefore, it would be obvious to one of ordinary skill in the art that a second active component could be added to the external aqueous phase of the mixed emulsion of the patented claims. Accordingly, the instant claim 19 is obvious over the patented claim 1

in view of Nadaud et al. (US 5,567,426), and thus is not patentably distinct over the US 7,101,931 B2 patent.

Furthermore, Claims 20 and 26 of the instant claims define solubility parameters for the nonionic surfactant or amphiphilic polymer present in the internal oily phase and the nonionic surfactant, nonionic amphiphilic polymer or anionic amphiphilic polymer present in the external aqueous phase. While these parameters are not specified in the patented claims, it would be obvious to one skilled in the art to choose a surfactant or polymer based on the solubility of the surfactant or polymer in the desired phase. Accordingly, the instant claims 20 and 26 are obvious over the patented claim 1 in view of Nadaud et al. (US 5,567,426), and thus are not patentably distinct over the US 7,101,931 B2 patent.

Claims 21-23, and 32 of the instant claims specify optimized weight percentage ratios for the nonionic surfactant or nonionic amphiphilic polymer, the hydrophilic active material in the internal aqueous phase, the oil to aqueous phase ratio of the water/oil inverse emulsion, and the weight ratio of the inverse emulsion to the external aqueous phase. The weight % ratios for components in the multiple emulsion of the patented claims 1, 5 and 7 substantially overlap with the weight % ratios of the instant claims, except they do not give a weight % for the hydrophilic active material in the internal aqueous phase. However, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to determine a workable or optimized weight % ratio of active material to get its desired effect. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Accordingly, the instant claims 21-23 and 32 are obvious over the patented claims 1, 5 and 7 in view of Nadaud et al. (US 5,567,426), and thus are not patentably distinct over the US 7,101,931 B2 patent.

Claims 30-31 of the instant claims are directed to formulations of multiple emulsions that further contain a thickening polymer in the external aqueous phase. Claim 31 further indicates the polymer is present in 0.1 to 2% by weight of the external aqueous phase. While the patented claims do not disclose adding a thickening polymer to the external aqueous phase, it is commonly known by one of ordinary skill in the art that thickening polymers can be added to the aqueous phase of an emulsion to increase its viscosity and stability. For example, Nadaud et al. gives several examples of multiple emulsions where a gelling agent, such as xanthan gum or Carbopol 980®, is used to increase the viscosity of the multiple emulsion (see column 2, lines 55-67 and examples). A polymeric gelling agent is considered to be analogous to a thickening polymer, because they include the same polymers, and they both refer to polymers that increase the viscosity of the composition. Nadaud et al. also discloses examples where a gelling agent is present in the desired range of 0.1-2% by weight of the external aqueous phase (see examples 1-4 and 5-12). Accordingly, the instant claims 30-31 are obvious over the patented claim 1 in view of Nadaud et al. (US 5,567,426), and thus are not patentably distinct over the US 7,101,931 B2 patent.

Claims 24-25 and 33-36 of the instant claims are directed to formulations further comprising a salt or sugar additive in the internal aqueous phase, a salt or sugar

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additive in the external aqueous phase, an external oily phase, or a dispersed solid in the external aqueous phase. The mixed emulsions of claims 8-11 of the patented claims further contain the same components, except they do not disclose adding a salt or sugar to the internal aqueous phase. However the term "comprising" of the patented claims does not preclude these components from being present. Salts and sugars are frequently added to the internal aqueous phase of emulsions to stabilize w/o emulsions (see Nadaud et al., column 6, lines 31-36). Therefore, it would be obvious to one of ordinary skill in the art, at the time of the invention, to add the proper amount of salt additive to stabilize the invention. Accordingly, the instant claims 24-25 and 33-36 are obvious over the patented claims 8-11 in view of Nadaud et al. (US 5,567,426), and thus are not patentably distinct over the US 7,101,931 B2 patent.

8. Claims 27-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. U.S. Patent No. 7,101,931 B2 in view of Nadaud et al. (US 5,567,426) and in further view of Yeung et al. (WO 00/35961) published on 5/22/2000. Claims 27-29 of the instant claims are directed to formulations comprising multiple emulsions as described above for claim 19, but further comprise a thermothickening polymer in the external aqueous phase. Claim 28 further specifies that the thermothickening polymer exhibit a rise in viscosity between 25 and 80°C such that the increase in viscosity has a \log_{10} ratio of at least 1. Claim 29 specifies that the thermothickening polymer is present in 0.2 –10% by weight of the external aqueous phase. The multiple emulsion of the patented claim 1 in view of Nadaud et al.

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is considered to render obvious the multiple emulsion of the instant claim 19 as discussed above; however, thermothickening polymers are not mentioned. Yeung et al. discloses that thermothickening polymers formed in inverse water-in-oil emulsions that can be utilized in cosmetic applications to control the viscosity with varying temperatures (see abstract, page 1, lines 17-24, and page 3, lines 23-29). Yeung et al. gives examples of polymers in aqueous solutions exhibiting a rise in viscosity between 25 and 80°C such that the increase in viscosity has a \log_{10} ratio of at least 1 in Figure 2. Therefore, it would be obvious to one of ordinary skill of art, at the time of the invention, to use an optimized amount of thermothickening polymer to control the rheology of the composition with temperature. Accordingly, the instant claims 27-29 are obvious over the patented claim 1 in view of Nadaud et al. (US 5,567,426) and in further Yeung et al. (WO 00/35961), and thus are not patentably distinct over the US 7,101,931 B2 patent.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-24, 26, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Herb et al. (US 5,589,177).

Claim 19 is directed to a cosmetic or dermatological formulation comprising a multiple emulsion, which comprises an internal aqueous phase containing at least one

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hydrophilic active material, dispersed in an internal oily phase containing at least one nonionic surfactant or at least one amphiphilic polymer, the whole being dispersed in an external aqueous phase containing at least one soluble or dispersed active material and at least one nonionic surfactant, nonionic amphiphilic polymer, or anionic amphiphilic polymer. Claim 21 is interpreted to require that the nonionic surfactant or nonionic amphiphilic polymer is present in 2 to 10% by weight of the **external aqueous phase**. Claim 22 specifies that active component in the internal aqueous phase is present in 0.1 to 50% by weight of the phase. Claim 23 specifies that the inverse emulsion has an aqueous to oil phase weight ratio between 10/90 and 90/10. Claim 32 specifies that the weight ratio of the inverse emulsion to the external aqueous phase be between 30/70 and 90/10.

Herb et al. discloses a water-in-oil-in-water multiple emulsion comprising about 40 to 99% by weight of an external aqueous phase, and 1 to 60% by weight of a w/o emulsion (see column 4, lines 16-22). The w/o emulsion comprises 1 to 95% by weight of the o/w emulsion of an internal aqueous phase comprising an active component in preferably 0.1 to 30% by weight of the o/w emulsion, an oily phase in 0.5 to 95% by weight of the o/w emulsion, and a silicone-free nonionic surfactant or polymeric surfactant in 0.1 to 20% by weight (see column 4, lines 23-37, column 6, lines 49-54, and column 19, lines 1-2). The external aqueous phase comprises a nonionic surfactant and a second active component (see column 4, lines 33-44). The term "comprising" in the instant claims is interpreted to be broad and open-ended. Therefore,

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the formulations of the instant claims can be considered to contain only the multiple emulsions and Herb et al. meets all of the limitations of claims 19, 21-23 and 32.

Claim 20 further specifies that the nonionic surfactant or amphiphilic polymer present in the internal oily phase simultaneously satisfies the following two conditions: (1) when they are mixed with the internal oily phase at a concentration between 0.1 and 10% by weight of the phase at 25°C, they are in solution form in the whole or part of the concentration range indicated; and (2) when they are mixed with the internal aqueous phase, at a concentration between 0.1 and 10% by weight of the phase at 25°C, they are dispersed in the whole or part of the concentration range indicated. Claim 26 further specifies similar conditions for the surfactant or polymer present in the external aqueous phase, except they are soluble in the external aqueous phase and dispersed in the internal aqueous phase. Herb et al. discloses that the nonionic surfactants in the internal oily phase have a "hydrophilic-lipophilic balance" or HLB value of 0.1 to 10 (see column 19, lines 7-9), and the that nonionic surfactants in the external aqueous phase have HLB values greater than 10 (see column 22, lines 28-35). HLB values are well-known in the art, and are related to the solubility of the surfactant, where surfactants with HLB values of 10 or less are considered to oil soluble, and HLB values greater than 10 tend to be water-soluble (see column 4, lines 9-15). Therefore, the nonionic surfactants taught by Herb et al. would be expected to meet the limitations of the instant claims 20 and 26.

Claim 24 of the instant claims further requires the internal aqueous phase to include an additive selected from the group consisting of alkali metal halides, alkaline-

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earth metal halides, alkali metal sulfates, alkaline-earth metal sulfates, sugars and polysaccharides. Herb et al. indicates that the internal aqueous phase can further comprise additional active components or water-soluble compounds, and mentions the sugars fructose, glucose as potential active components (see column 9, lines 7-10 and column 11, lines 23-26). In addition, Herb et al. gives examples of w/o emulsions that can be incorporated into w/o/w emulsions that comprise a sugar in the internal aqueous phase in addition to another active component (see examples 96-111, and column 42 lines 36-48). Therefore, Herb et al. meets the limitations of the instant claim 24.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 24-25 and 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Herb et al. (US 5,589,177) as applied to claims 19 above, and further in view of Bee et al. (US 4,985,250).

Claim 19 is directed to cosmetic or dermatological formulations of multiple emulsions as described above. Claim 24 further requires a salt or sugar additive in the internal aqueous phase as discussed above. Claim 25 further requires the salt additive to be present at a concentration of 0.05 to 1 mol/L, or that the sugar is present at

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concentration that would result in the same osmotic pressure in the internal aqueous phase as if a salt were present in 0.05 to 1 mol/L. Claim 25 further indicates the osmotic pressure of the external aqueous phase and internal aqueous phase are balanced by adding another salt or sugar additive to external aqueous phase.

Herb et al. is important for its disclosure of the multiple emulsions as applied to claim 19. However, Herb et al. does not disclose any specific embodiments where the salt or sugar additive is in the desired range of the internal aqueous phase.

Furthermore, Herb et al. also does not disclose any embodiments where a salt or sugar additive is added to external aqueous phase to balance the osmotic pressure of the aqueous phases.

Bee et al., directed to w/o/w multiple emulsions for use in creams and cosmetics in which the external continuous phase is gelled, is important for its disclosure of the presence of osmotic pressure components in multiple emulsions (see abstract). Bee et al. indicates that the osmotic pressure components are used to draw water from the external aqueous phase into the internal aqueous phase (see abstract). Bee et al. also explicitly states that that the external aqueous phase of the multiple emulsion contains an osmotic pressure component to control the rate of osmosis until osmotic balance is achieved (see column 1, lines 55-60) and that examples of osmotic pressure components are salts such as sodium chloride and sugar such as glucose or sucrose (see column 5, lines 12-14). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made that a salt or sugar components could be added to the internal aqueous phase to draw water from the external aqueous phase,

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and that a second salt or sugar component could be added to external aqueous phase to balance the osmotic pressure and stop the flow of water from the external to the internal aqueous phase.

11. Claims 19 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herb et al. (US 5,589,177) as applied to claim 19 above, and further in view of Nadaud et al. (US 5,567,426).

Claim 19 is directed to cosmetic or dermatological formulations of multiple emulsions as described above. Claim 30 further requires a thickening polymer to be present in the external aqueous phase. Claim 31 further indicates the polymer is present in 0.1 to 2% by weight of the external aqueous phase.

Herb et al. is important for its disclosure of the multiple emulsions as applied to claim 19. However, Herb et al. does not include any embodiments where a thickening polymer is present in the external phase. Furthermore, Herb et al. specifically indicates that polymeric gelling agents, which are analogous to thickening polymers as described above, are not present in the external aqueous phase (see column 4, lines 44-45).

Nadaud et al. is important for its disclosure of gelled w/o/w multiple emulsions, where a gelling agent is present in the external aqueous phase (see abstract and column 2, lines 55-67). Gelling agents are commonly known in the art to increase the viscosity of emulsions. Xanthan gums, known thickening polymers, are specifically listed as potential gelling agents. Nadaud et al. also discloses examples where a gelling agent is present in the desired range of 0.1-2% by weight of the external

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aqueous phase (see examples 1-4 and 5-12). Therefore, it would be obvious to one of ordinary skill in the art, at the time the invention was made, to add a gelling agent or thickening polymer to the external aqueous phase to increase the viscosity of a multiple emulsion.

12. Claims 19 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herb et al. (US 5,589,177) as applied to claim 19 above, and further in view of Yeung et al. (WO 00/35961), published on 5/22/2000.

Claims 27-29 of the instant claims are directed to formulations comprising multiple emulsions as described above for claim 19, but further comprise a thermothickening polymer in the external aqueous phase. Claim 28 further specifies that the thermothickening polymer exhibit a rise in viscosity between 25 and 80°C such that the increase in viscosity has a \log_{10} ratio of at least 1. Claim 29 specifies that the thermothickening polymer is present in 0.2 –10% by weight of the external aqueous phase.

Herb et al. is important for its disclosure of the multiple emulsions as applied to claim 19. However, Herb et al. does not disclose any embodiments in which thermothickening polymers added to the external aqueous phase.

Yeung et al. is important for its disclosure of thermothickening polymers formed in inverse water-in-oil emulsions that can be utilized in cosmetic applications to control the viscosity with varying temperatures (see abstract, page 1, lines 17-24, and page 3, lines 23-29). As mentioned above, Yeung et al. gives examples of polymers in aqueous

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solutions exhibiting a rise in viscosity between 25 and 80°C such that the increase in viscosity has a \log_{10} ratio of at least 1 in Figure 2. Therefore, it would be obvious to one of ordinary skill of art, at the time of the invention, to use an optimized amount of thermothickening polymer to control the rheology of a multiple emulsion composition with temperature.

13. Claims 19 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herb et al. (US 5,589,177) as applied to claim 19 above, and further in view of Nicoll et al. (US 5,188,831).

Claims 35-36 of the instant claims are directed to formulations comprising multiple emulsions as described above for claim 19, but further comprise at least one dispersed solid in the external aqueous phase. Claim 36 specifies that the dispersed solid be present in 1 to 50% by weight of the external aqueous phase.

Again, Herb et al. is important for its disclosure of the multiple emulsions as applied to claim 19. Herb et al. also discloses that a second active component can be added to the external phase in 0 to 30 % by weight of the phase. However, Herb et al. indicates that this active ingredient is typically water-soluble, and while the disclosure does not preclude dispersed solid active components from being present in the external aqueous phase, it does not disclose any embodiments in which they are present.

Nicoll et al. is important for its disclosure of sunscreen compositions comprising water-dispersible ultra-fine titanium dioxide (the dispersed solid of interest) and oil-dispersible ultra-fine titanium dioxide (see abstract). Nicoll et al. also indicates that

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emulsions are a particularly convenient forms of the compositions, and that oil-in-water emulsions are possible (see column 4, lines 8-14). It can be conceived that if oil phase of the o/w emulsion contains an internal aqueous phase, then the water phase of the o/w emulsion is analogous to the external aqueous phase of the instant invention.

Therefore, it would be obvious to one of ordinary skill in the art to add a dispersible solid such as titanium to dioxide to the external aqueous phase of the multiple emulsions to obtain a cosmetic formulation for protection against the sun.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 274-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

Jody Karol



**MICHAEL MELLER
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